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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,468	03/09/2004	Leo B. Kriksunov	2004.10LK	2287
40621	7590	03/13/2006		
PASTEL LAW FIRM CHRISTOPHER R. PASTEL 8 PERRY LANE ITHACA, NY 14850-9267			EXAMINER PRASAD, SONAL	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/796,468		KRIKSUNOV, LEO B.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Sonal Prasad		3767	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/24/04</u>   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims **1, 6, & 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Staylor et al (US 6,585,685 B2) in view of Bernard et al. (US 2005/0215941 A1.) Staylor et al discloses a method of hypodermically delivering a drug into a patient's body through a patient's skin, said method comprising: providing a jet injection device (claim 1, line 1) capable of delivering the drug into the patient's body (abstract, line 5) through the skin as a jet of liquid (abstract, line 5), and delivering the drug into the patient's body through the skin as a jet of liquid (abstract.) The claim differs from Staylor et al in disclosing the electrical circuit. Bernard et al discloses the device forming an open electrical circuit between the patient's body and said jet injection device, providing an electric impedance monitor connected to said electrical circuit, starting measuring the electrical impedance between patient's body and said jet injection device, closing said electrical circuit through said jet of liquid, detecting a change in electrical impedance during the delivery of the drug into the patient's body. (Detailed description [0051]). It would have been obvious at the time of invention to one of ordinary skill in that art to include the electrical circuit disclosed in Staylor et al as taught by Bernard et al to improve the performance of the device.

3. Regarding claim 6, Staylor et al discloses a method of hypodermically injecting a drug into a patient's body and monitoring the injection success, comprising the steps of: providing a means for hypodermic jet injection of a drug (claim 1, line 1), delivering the drug utilizing said means for hypodermic jet injection of the drug into the patient's body as a jet of liquid (abstract, line 5), The claim differs from Staylor et al in disclosing the electrical circuit. Bernard et al discloses providing a means for monitoring electric impedance between said means for hypodermic jet injection of a drug and patient's body, forming an open electrical circuit between the patient's body and said means for hypodermic jet injection of a drug, measuring electric impedance between said means for hypodermic jet injection of a drug and patient's body using said means for monitoring electric impedance, detecting changes in electric impedance. (Detailed description [0051]). It would have been obvious at the time of invention to one of ordinary skill in that art to include the electrical circuit disclosed in Staylor et al as taught by Bernard et al to improve the performance of the device. Regarding claim 10, Staylor discloses a jet injector drug delivery apparatus comprising: a jet injection device. (claim 1, line 1). The claim differs from Bernard et al from Staylor et al in disclosing the electrical monitor. Bernard et al discloses an electric impedance monitor having electric connection to a patient's body and to said jet injection device, electrically coupled to said electric impedance monitor. (Detailed description [0051]). It would have been obvious at the time of invention to one of ordinary skill in that art to include the electrical circuit

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disclosed in Staylor et al as taught by Bernard et al to improve the performance of the device.

4. Claims 2-5,7-9, & 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staylor et al (US 6,585,685 B2) in view of Fogarty et al. (US 2002/0059938 A1.) The claims differ from Staylor in disclosing a signal. Fogarty et al discloses the method and the jet injector with a signal that is audible, visual, and both audible and visual. (Detailed description 182 & 229). It would have been obvious at the time of invention to one of ordinary skill in that art to include the electrical circuit disclosed in Staylor et al as taught by Fogarty et al to improve the performance of the signal.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonal Prasad whose telephone number is 571-272-3383. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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